

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 1: Identification

Product Name Lactose Monohydrate NF (Spray-dried)
Commercial Name Not available
Product Use Excipient material used in pharmaceutical applications
Restrictions On Use Not available.
Product Code 30-3329
Company PCCA
9901 South Wilcrest
Houston, TX 77099
Phone: 1-800-331-2498
Fax: 1-800-874-5760

In case of emergency contact:
CHEMTREC (24hr) 1-800-424-9300

Section 2: Hazard(s) Identification

OSHA Haz Com: COMBUSTIBLE DUSTS
CFR 1910.1200
Signal Word WARNING
Hazard Statement(s) May form combustible dust concentrations in air.
Pictogram(s) or Symbol(s)

Precautionary Statement(s):

Prevention Not available.
Response Not available.
Storage Keep container tightly closed. Keep away from heat, hot surfaces, sparks, open flames and other ignition sources. No smoking. Prevent dust accumulation.
Disposal Not available.

Section 3: Composition/Information on Ingredients

Substance/Mixture Substance
Components Lactose Monohydrate NF (Spray-dried)
% By Weight 100
CAS# 64044-51-5
Molecular Weight 360.31 g/mole
Chemical Formula C₁₂H₂₂O₁₁.H₂O
Synonym(s) Milk sugar, SHEFFIELD LACTOSE MONO 313 25KG

Mixtures

Name	CAS#	% by Weight	TLV/PEL	LC50/LD50
			Not available	Not available

Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Section 4: First-Aid Measures

Inhalation	Remove victim to fresh air and keep at rest in a position comfortable for breathing. If not breathing, if breathing is irregular or if respiratory arrest occurs, provide artificial respiration or oxygen by trained personnel. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation. Get medical attention if adverse health effects persist or are severe. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Skin Contact	Flush contaminated skin with plenty of water. Remove contaminated clothing and shoes. Get medical attention if symptoms occur. Wash clothing before reuse. Clean shoes thoroughly before reuse.
Eye Contact	Immediately flush eyes with plenty of water, occasionally lifting the upper and lower eyelids. Check for and remove any contact lenses. Continue to rinse for at least 10 minutes. Get medical attention if irritation occurs.
Ingestion	Wash out mouth with water. Remove dentures if any. Remove victim to fresh air and keep at rest in a position comfortable for breathing. If material has been swallowed and the exposed person is conscious, give small quantities of water to drink. Stop if the exposed person feels sick as vomiting may be dangerous. Do not induce vomiting unless directed to do so by medical personnel. If vomiting occurs, the head should be kept low so that vomit does not enter the lungs. Get medical attention if adverse health effects persist or are severe. Never give anything by mouth to an unconscious person. If unconscious, place in recovery position and get medical attention immediately. Maintain an open airway. Loosen tight clothing such as a collar, tie, belt or waistband.
Symptoms/Effects	
Acute	Eye contact : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes. Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs. Skin contact : No known significant effects or critical hazards. Ingestion : No known significant effects or critical hazards.
Delayed	Eye contact : Adverse symptoms may include the following: irritation, redness Inhalation : Adverse symptoms may include the following: respiratory tract irritation, coughing Skin contact : No specific data. Ingestion : Irritating to mouth, throat and stomach.

Immediate Medical Attention

Notes to physician : Treat symptomatically. Contact poison treatment specialist immediately if large quantities have been ingested or inhaled. Specific treatments : No specific treatment. Protection of first-aiders : No action shall be taken involving any personal risk or without suitable training. It may be dangerous to the person providing aid to give mouth-to-mouth resuscitation.

Section 5: Fire-Fighting Measures**Suitable Extinguishing Media**

Use dry chemical powder.

Unsuitable Extinguishing Media

Avoid high pressure media which could cause the formation of a potentially explosible dust-air mixture.

Products of Combustion

May form explosible dust-air mixture if dispersed. Decomposition products may include the following materials: carbon dioxide, carbon monoxide

Firefighters Special Equipment and Precautions

Promptly isolate the scene by removing all persons from the vicinity of the incident if there is a fire. No action shall be taken involving any personal risk or without suitable training. Move containers from fire area if this can be done without risk. Use water spray to keep fire-exposed containers cool. Fire-fighters should wear appropriate protective equipment and self-contained breathing apparatus (SCBA) with a full face-piece operated in positive pressure mode.

Section 6: Accidental Release Measures

Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

For non-emergency personnel : No action shall be taken involving any personal risk or without suitable training. Evacuate surrounding areas. Keep unnecessary and unprotected personnel from entering. Do not touch or walk through spilled material. Shut off all ignition sources. No flares, smoking or flames in hazard area. Avoid breathing dust. Provide adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Put on appropriate personal protective equipment. For emergency responders : If specialized clothing is required to deal with the spillage, take note of any information in Section 8 on suitable and unsuitable materials. See also the information in "For non-emergency personnel". Environmental precautions : Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers. Inform the relevant authorities if the product has caused environmental pollution (sewers, waterways, soil or air). Methods and materials for containment and cleaning up
Small spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Vacuum or sweep up material and place in a designated, labeled waste container. Dispose of via a licensed waste disposal contractor. Large spill : Move containers from spill area. Use spark-proof tools and explosion-proof equipment. Approach release from upwind. Prevent entry into sewers, water courses, basements or confined areas. Vacuum or sweep up material and place in a designated, labeled waste container. Avoid creating dusty conditions and prevent wind dispersal. Dispose of via a licensed waste disposal contractor. Note: see Section 1 for emergency contact information and Section 13 for waste disposal.

Section 7: Handling and Storage

Protective measures : Put on appropriate personal protective equipment (see Section 8). Do not ingest. Avoid contact with eyes, skin and clothing. Avoid breathing dust. Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Prevent dust accumulation. Use only with adequate ventilation. Wear appropriate respirator when ventilation is inadequate. Keep in the original container or an approved alternative made from a compatible material, kept tightly closed when not in use. Electrical equipment and lighting should be protected to appropriate standards to prevent dust coming into contact with hot surfaces, sparks or other ignition sources. Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Empty containers retain product residue and can be hazardous. Do not reuse container. Advice on general occupational hygiene : Eating, drinking and smoking should be prohibited in areas where this material is handled, stored and processed. Workers should wash hands and face before eating, drinking and smoking. Remove contaminated clothing and protective equipment before entering eating areas. See also Section 8 for additional information on hygiene measures. Conditions for safe storage, including any incompatibilities : Store in accordance with local regulations. Store in a segregated and approved area. Store in original container protected from direct sunlight in a dry, cool and well-ventilated area, away from incompatible materials (see Section 10) and food and drink. Eliminate all ignition sources. Separate from oxidising materials. Keep container tightly closed and sealed until ready for use. Containers that have been opened must be carefully resealed and kept upright to prevent leakage. Do not store in unlabeled containers. Use appropriate containment to avoid environmental contamination. See Section 10 for incompatible materials before handling or use.

Section 8: Exposure Controls/Personal Protection

Exposure Limits	Not available.
Engineering Controls	Use only with adequate ventilation. If user operations generate dust, fumes, gas, vapor or mist, use process enclosures, local exhaust ventilation or other engineering controls to keep worker exposure to airborne contaminants below any recommended or statutory limits. The engineering controls also need to keep gas, vapor or dust concentrations below any lower explosive limits. Use explosion-proof ventilation equipment. Environmental exposure controls : Emissions from ventilation or work process equipment should be checked to ensure they comply with the requirements of environmental protection legislation. In some cases, fume scrubbers, filters or engineering modifications to the process equipment will be necessary to reduce emissions to acceptable levels.

Safety Data Sheet

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Personal Protection

Hygiene measures : Wash hands, forearms and face thoroughly after handling chemical products, before eating, smoking and using the lavatory and at the end of the working period. Appropriate techniques should be used to remove potentially contaminated clothing. Wash contaminated clothing before reusing. Ensure that eyewash stations and safety showers are close to the workstation location.

Eye/face protection : Safety eyewear complying with an approved standard should be used when a risk assessment indicates this is necessary to avoid exposure to liquid splashes, mists, gases or dusts. If contact is possible, the following protection should be worn, unless the assessment indicates a higher degree of protection: safety glasses with side-shields. If operating conditions cause high dust concentrations to be produced, use dust goggles.

Skin protection

Hand protection : Chemical-resistant, impervious gloves complying with an approved standard should be worn at all times when handling chemical products if a risk assessment indicates this is necessary. Considering the parameters specified by the glove manufacturer, check during use that the gloves are still retaining their protective properties. It should be noted that the time to breakthrough for any glove material may be different for different glove manufacturers. In the case of mixtures, consisting of several substances, the protection time of the gloves cannot be accurately estimated.

Body protection : Personal protective equipment for the body should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Other skin protection : Appropriate footwear and any additional skin protection measures should be selected based on the task being performed and the risks involved and should be approved by a specialist before handling this product.

Respiratory protection : Based on the hazard and potential for exposure, select a respirator that meets the appropriate standard or certification. Respirators must be used according to a respiratory protection program to ensure proper fitting, training, and other important aspects of use.

Section 9: Physical and Chemical Properties

Appearance	Solid. (white powder)		
Odor	Odorless		
Odor Threshold	Not available.		
Melting Point	Not available.	pH	Not available.
Freezing Point	Not available.	Vapor Pressure	Not available.
Boiling Point/Range	Not available.	Vapor Density	Not available.
Decomposition temperature	Not available.	Viscosity	Not available.
Partition Coefficient: n-octanol/water	Not available.	Evaporation Rate	Not available.
Flash Point	93.33 °C (199.99 °F)	Autoignition temperature	Not available
Flammability	Not available.	Flammability or Explosive Limits:	
		Lower	Not available.
		Upper	Not available.
Solubility(ies)	Not available		
Other	Relative density : 1.0		

Section 10: Stability and Reactivity

Reactivity	No specific test data related to reactivity available for this product or its ingredients.
Chemical Stability	The product is stable.
Hazardous Polymerization	Under normal conditions of storage and use, hazardous reactions will not occur
Conditions to Avoid	Avoid the creation of dust when handling and avoid all possible sources of ignition (spark or flame). Take precautionary measures against electrostatic discharges. To avoid fire or explosion, dissipate static electricity during transfer by grounding and bonding containers and equipment before transferring material. Prevent dust accumulation
Incompatible Materials	oxidising materials
Hazardous Decomposition Products	Under normal conditions of storage and use, hazardous decomposition products should not be produced.

Section 11: Toxicological Information
RTECS OD9625000

Acute Toxicity

Not available.

Skin Corrosion/Irritation

Not available.

Serious Eye Damage/Irritation

Not available.

Respiratory or Skin Sensitization

Not available.

Germ Cell Mutagenicity

Not available.

Carcinogenicity

Not available.

Reproductive Toxicity

Not available.

**Safety Data Sheet**

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

Routes of Entry

Inhalation. Ingestion.

Symptoms Related to Exposure

Eye contact : Adverse symptoms may include the following: irritation, redness; Inhalation : Adverse symptoms may include the following: respiratory tract irritation, coughing; Ingestion : Irritating to mouth, throat and stomach.

Potential Health Effects

Eye contact : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the eyes. Inhalation : Exposure to airborne concentrations above statutory or recommended exposure limits may cause irritation of the nose, throat and lungs.

Target Organ(s) Repeated or prolonged inhalation of dust may lead to chronic respiratory irritation.

Section 12: Ecological Information**Ecotoxicity**

Not available

Persistence and Degradability

Not available.

Bioaccumulative Potential

Not available.

Mobility in Soil

Not available.

Other Adverse Effects

Not available.

Section 13: Disposal Considerations**Waste Disposal**

The generation of waste should be avoided or minimized wherever possible. Disposal of this product, solutions and any by-products should at all times comply with the requirements of environmental protection and waste disposal legislation and any regional local authority requirements. Dispose of surplus and non-recyclable products via a licensed waste disposal contractor. Waste should not be disposed of untreated to the sewer unless fully compliant with the requirements of all authorities with jurisdiction. Waste packaging should be recycled. Incineration or landfill should only be considered when recycling is not feasible. This material and its container must be disposed of in a safe way. Care should be taken when handling emptied containers that have not been cleaned or rinsed out. Empty containers or liners may retain some product residues. Avoid dispersal of spilled material and runoff and contact with soil, waterways, drains and sewers.

Disposal of Container

Not available.

Other Considerations

Not available.

Section 14: Transport Information**DOT Classification**

Not classified as dangerous in the meaning of transport regulations.

Section 15: Regulatory Information**Regulations**

Federal and State Regulations: No products were found.

Other

Not available.

Section 16: Other Information



Safety Data Sheet

30-3329

For Compliance with OSHA 29 CFR 1910.1200 and ANSI Z400.1-1998

The information contained herein is based on our state of knowledge at the above - specified date. It refers solely to the product indicated and constitutes no guarantee of particular quality. It is the duty of the user to ensure that this information is appropriate and complete with respect to the specific use intended.